REPORT TO CONGRESS

MEDICARE THERAPEUTIC SHOE DEMONSTRATION

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Secretary
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MEDICARE THERAPEUTIC SHOE DEMONSTRATION
EXECUTIVE SUMMARY

The Omnibus Budget Reconciliation Act (OBRA) of 1987, P.L. 100-203, Section 4072 mandated a demonstration project under which clinically eligible diabetic Medicare beneficiaries would receive Medicare Part B coverage for therapeutic shoes. Congress also mandated an evaluation of the demonstration to determine whether a therapeutic shoe benefit would be cost-effective and should be introduced as a regular Part B benefit. The targeted Medicare beneficiaries include about 450,000 persons who have diabetes and have manifested severe foot disease or evidence of being at risk of severe foot disease. In the past, this group has had high rates of hospitalization for severe foot infections, high amputation rates, and high mortality rates. Clinicians believe that when such patients wear therapeutic shoes, the incidence of complications decreases. Thus, efforts to encourage the use of therapeutic shoes should have a potential for being cost-effective.

The demonstration originally allowed payment for one pair of custom-molded or depth-inlay shoes per year (including one pair of inserts for the depth-inlay shoes). The law mandated the prices and provides for annual adjustment for inflation increases. In 1990 the prices are $305 for custom-molded shoes, $102 for depth-inlay shoes, and $51 for inserts. However, the demonstration benefit was expanded by OBRA 1989, P.L. 101-239, to include two pairs of replacement inserts during the year or modifications to the shoes.

The law required that a report on the benefit's cost-effectiveness be submitted by October 1, 1990. If the report showed that the demonstration benefits were cost-effective, the law provided for therapeutic shoe coverage to be introduced into the regular Medicare program in November 1990. If the report did not show cost-effectiveness, the demonstration would continue until October 1992. If the final Report to Congress in April 1, 1993 is unable to show that the benefit was not cost-effective, therapeutic shoe coverage is to be introduced into the regular Medicare program in May 1, 1993.

The term "cost-effective" is central to the demonstration and its evaluation. The evaluation will not determine whether the therapeutic shoe benefit is clinically effective (though the shoes are not expected to be cost-effective unless they are also clinically effective). To be cost-effective, the cost to Medicare of the therapeutic shoes must be less than the savings that result from reduced use of other Medicare-covered services (such as hospital stays) that occurs because the therapeutic shoes help to prevent foot disease. The evaluation will measure

cost-effectiveness by comparing the costs to Medicare of a group who receive the therapeutic shoe benefit with a comparable group that does not receive the benefit. A broader definition of cost-effectiveness, not subject to evaluation in this demonstration, would take into consideration other costs such as employability and use of support services, as well as concerns for the beneficiaries' well-being and level of functioning.

Experience gained in the demonstration to date is insufficient to indicate whether the benefit is cost-effective. Therefore, this report provides background on the demonstration, the clinical arguments as to why Medicare should cover therapeutic shoes, the legislative history behind the demonstration, a description of how the demonstration was implemented, and a description of what is known about the diabetic population at risk of severe foot disease and how their characteristics affect the likelihood of the benefit being cost-effective.

For the benefit to be clinically effective, the following conditions must also be met: the shoes must be fitted and dispensed by a practitioner skilled in fitting shoes to the diabetic foot and the shoes must be part of a comprehensive plan of care for the diabetes, including appropriate foot care. The demonstration was designed to fulfil these conditions. (The patients must also wear the shoes.)

The key features of the demonstration project are as follows:

- The demonstration is taking place in California, Florida, and New York.
- Eligibility is limited to beneficiaries who meet specified clinical criteria and whose physicians certify eligibility and prescribe shoes (the target sample is 27,400 beneficiaries).
- Applicants must apply to the demonstration and have their eligibility reviewed.
- To meet evaluation requirements, half of the eligible applicants are randomly selected to receive coverage while the other half serve as a control group and are eligible only for current Medicare coverage. Payment authorization and instructions are provided to covered beneficiaries.

- Shoes are supplied by suppliers who have been authorized by the Health Care Financing Administration (HCFA). All suppliers must accept assignment of benefits. Suppliers file claims with and are reimbursed by HCFA.

Early results from the demonstration show that the demonstration was implemented following the congressional mandate, with the participation of over 3,000 physicians, over 350 shoe suppliers, and nearly 1,000 eligible beneficiaries.

The evaluation will compare the Medicare costs of the group who receive the demonstration benefit (including shoe costs) with those of the control group during a followup period of 1 or more years to establish whether the benefit results in higher, lower, or unchanged costs. A supplementary analysis will also compare the group who receive the demonstration benefit with similar beneficiaries in States where the benefit is not being offered.

If the benefit is to be cost-effective, a number of conditions must be met. The first of these is the provision of the benefit to a targeted group at risk of developing complications. Evidence from the demonstration shows that a very high risk group was enrolled in the first 4 months. However, if the enrolled group is not broadened to include less severely affected beneficiaries, there is a possibility that sample sizes will not be reached and it may be difficult to show cost-effectiveness, even if it occurs. Second, the rates of foot disease will affect Medicare costs. It is clear that medical treatment of foot disease is replacing surgical treatment (especially amputation), and thus the relative costs of these two approaches will be an important factor in total Medicare costs. Third, the relative rates of prescriptions for custom-molded or depth-inlay shoes also will affect cost-effectiveness because custom-molded shoes cost twice as much as depth-inlay shoes. Early results show that 59 percent of the participants were prescribed custom-molded shoes, a higher rate than expected. It is possible that this rate of prescription of custom-molded shoes is related to the severity of problems of enrollees. Since there is no evidence of differential clinical effectiveness for custom-molded and depth-inlay shoes, extensive use of the more expensive custom-molded shoes in the demonstration will reduce the probability that the benefit will be cost-effective.

The cost-effectiveness of the benefit also depends on whether Medicare beneficiaries purchase and use therapeutic shoes in the absence of the demonstration. More than one third of the early applicants were already wearing some type of therapeutic shoe when they applied for the benefit, a higher rate than expected. If the demonstration's control group continues to purchase therapeutic shoes at this rate, differences in outcomes between

the covered beneficiaries and control group beneficiaries will be small, and it may be difficult to measure differences in Medicare costs between the two groups.

For the evaluation to establish cost-effectiveness (or lack thereof), the demonstration will need to enroll a sufficient number of participants. A review of Medicare data and the literature suggest that there are between 415,000 and 470,000 eligible beneficiaries nationwide, with an adequate number in the demonstration States for estimating effects. Because early enrollment has been lower than expected, plans are underway to increase participation during the early part of 1990 in cooperation with the clinical community, to ensure that the evaluation will have an adequate data base for measuring cost-effectiveness. Very few primary care practitioners certified patient eligibility or prescribed therapeutic shoes in the first 4 months of the demonstration. More widespread participation by these physicians should yield a larger and more varied group of participating beneficiaries.

Because there is insufficient evidence at the present time to indicate whether the therapeutic shoe benefit is cost-effective, the demonstration needs to be continued for 2 more years, as provided by Congress in the enabling legislation.

I. BACKGROUND TO THE DEMONSTRATION AND EVALUATION DESIGN

A. INTRODUCTION

In 1987, Congress mandated a demonstration project under which clinically eligible diabetic Medicare beneficiaries would receive Medicare Part B coverage for therapeutic shoes (Omnibus Budget Reconciliation Act 1987 (OBRA 1987), P.L. 100-203, Section 4072). Congress also mandated an evaluation of the demonstration to decide whether a therapeutic shoe benefit would be cost-effective and should be introduced as a regular Part B benefit. Congress requested a report on cost-effectiveness of the demonstration benefit by October 1, 1990 and mandated that if cost-effectiveness had not been found at that time, the demonstration should be continued until October 31, 1992.

Diabetic patients with foot problems may develop severe infections that require extensive medical treatment in the hospital and can progress to the point at which leg amputation is necessary. Such patients also have high mortality rates. Many clinicians believe that properly fitted therapeutic shoes can limit or even prevent complications, though no case-control studies are available to show whether this clinical therapy is effective.[1] If the shoes are clinically effective for diabetic patients, they have the potential to be cost-effective by reducing hospital stays and physician visits.

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[1]It has been established that amputations can be averted by aggressive clinical approaches that include use of therapeutic shoes. Nonetheless, the role of therapeutic shoes in preventing amputations has not been clearly established.

The number of Medicare beneficiaries who are treated for severe diabetic foot disease has been estimated to be 87,000 or more, and the number at risk for severe foot disease has been estimated as between 415,000 and 471,000 in 1988. The Medicare costs of lengthy hospital stays for those who develop severe infections has been estimated to be between $12,000 and $20,000 per episode.

The term "cost-effective" is central to the demonstration and its evaluation. The evaluation will not determine whether the therapeutic shoe benefit is clinically effective (though the shoes are not expected to be cost-effective unless they are also clinically effective). To be cost-effective, the cost to Medicare of the therapeutic shoes must be less than the savings that result from reduced use of other Medicare-covered services (such as hospital stays) that occur because the therapeutic shoes help to prevent foot disease. We are not addressing broader questions of beneficiary well-being and social costs in the estimation of cost-effectiveness. The cost-effectiveness of the therapeutic shoe benefit depends largely on the clinical effectiveness of the shoes, which requires that they be fitted properly by skilled clinicians, that they be modified as necessary and maintained in good repair, and that patients wear them. Furthermore, the costs of the medical procedures that are

averted by the patients' wearing properly fitted therapeutic shoes must equal or exceed the cost of the shoes. Thus, both the rates at which procedures are averted and the averted costs of those procedures are important factors in whether the shoe benefit is cost-effective.

Two types of shoes are covered by the legislation: custom-molded shoes (which are built from a positive cast of the patient's foot) and depth-inlay shoes. Depth-inlay shoes are off-the-shelf shoes made with extra depth to accommodate inserts that are custom-made either directly from the patient's foot or from a cast of the foot. Custom-molded shoes cost twice as much as depth-inlay shoes. Thus, a further factor in cost-effectiveness is the relative rate at which the two types of shoes are supplied.

This mandated Report to Congress describes the design of the demonstration project and the associated evaluation of the cost-effectiveness of the shoe benefit for the Medicare program. The report was intended to indicate to Congress whether Medicare coverage of therapeutic shoes for Medicare beneficiaries with severe diabetic foot disease would be cost-effective. Because the demonstration did not begin until August 1, 1989, the sample that was enrolled as of November 25, 1989, is small. Hence, this report is limited to a description of the implementation of the demonstration and the characteristics of the beneficiaries and physicians who are participating. It is too early to indicate whether the demonstration benefit is cost-effective.

B. THE DIABETIC FOOT AND THERAPEUTIC SHOES

1. Prevalence of Severe Diabetic Foot Disease

Persons with long-term diabetes are at risk of developing severe foot problems. Patients typically develop ulcers on the soles of their feet that, if not promptly treated, can progress to serious infections and even gangrene, which may necessitate amputating the toe, foot, or leg. Foot conditions such as foot deformities and calluses--that are not serious for nondiabetic persons--can in fact cause severe foot disease in diabetic persons. Diabetic patients who have reduced sensation in the feet (peripheral neuropathy) or impaired gait that affects how they distribute their weight on their feet while walking can suffer trauma and ulcerations. Furthermore, the foot structure of diabetic patients may be altered by their diabetes (as in Charcot foot or previous amputations), either of which can lead to a change in gait and weight-bearing on surfaces not adapted to the purpose, which in turn can lead to tissue damage and ulceration. Finally, many diabetic patients have poor circulation, which can impede healing in damaged tissue. These aggregate problems have led to an amputation rate that is 15 times higher for diabetic than for nondiabetic persons. Indeed, one-half of all amputations in the United States involve patients with diabetes. Furthermore, once an amputation has occurred, the patient is at very high risk of repeat amputations.

Estimates of the number of diabetic Medicare beneficiaries who may be at risk of developing severe foot disease are scant (and variable). As we show in more detail in Chapter III, these

estimates vary from 87,000 to 471,000 beneficiaries nationwide. It is estimated that between 10,000 and 29,000 diabetic Medicare beneficiaries with severe foot disease may have a lower-extremity amputation each year.

There is some evidence that amputation rates have fallen (by 50 percent or more in the last decade) as clinicians improve medical treatments for foot infections. If the medical procedures that clinicians use to avert amputation were less expensive than amputation, there would be a lower probability that the added program costs of Medicare coverage for therapeutic shoes would be cost-effective. Nevertheless, hospital stays for medical treatment of foot infections may be lengthy. At present, the costs of such hospital stays are not documented. We anticipate that the demonstration will provide new information on the prevalence of foot disease among diabetic Medicare beneficiaries and the types of treatment received by these patients.

2. The Use of Therapeutic Shoes

Because diabetic patients often have reduced sensation in their feet--and may not notice, for instance, when they walk on foreign objects and, consequently, cut themselves--it is extremely important that they wear shoes at all times. Also, due to their poor sensation, the shoes that they do wear are frequently too tight, again causing considerable damage without the person's noticing. Finally, due to altered weight-bearing in the diabetic foot, ordinary shoes will not provide adequate protection or weight redistribution. Properly fitted therapeutic

protection from mechanical damage, do not rub and chafe, and provide the necessary weight-redistribution to protect foot tissue from damage.

Properly fitted shoes are only part of the appropriate care for the diabetic foot. Clinicians stress that diabetic patients must be under a comprehensive plan of care that includes blood sugar monitoring, as well as routine foot care that includes daily inspection of the feet for damage, daily washing, and clean hose. They must also sometimes undergo preventative surgery to correct deformities that could lead to problems.

Coverage of therapeutic shoes under Medicare Part B may reduce the incidence of severe diabetic foot disease if it increases access to and the use of therapeutic shoes as part of a comprehensive plan of care. There are no estimates of the rates of purchase or the use of therapeutic shoes by diabetic patients, nor of the types of therapeutic shoes that they wear. The experience of clinicians suggests that relatively few of the patients at risk of complications wear therapeutic shoes (so that the Medicare demonstration benefit could have a major impact on clinical outcomes and Medicare costs). The demonstration project will provide useful information on the rates of therapeutic shoe use. As reported in Chapter III, more than one third of the eligible applicants to the demonstration during its first 4 months already had therapeutic shoes, and 29 percent had received a prescription for therapeutic shoes from their physician in the year preceding their application to the demonstration. As discussed in Chapter III, these are much higher rates than expected.

The primary reasons cited by clinicians for the low use of therapeutic shoes are their cost, the lack of insurance coverage for the shoes, a lack of awareness about their need, and the unattractive appearance of the shoes. The demonstration is designed to have an effect on shoe-use rates by including them as a covered benefit. The demonstration may also serendipitously educate clinicians and patients about the importance of foot care for diabetic patients, thus increasing the awareness of and the use of therapeutic shoes among those at risk of foot disease. The demonstration, however, is unlikely to have an effect on such behavioral issues as patient compliance. Further, the evaluation will not address the compliance of patients with or the clinical effectiveness of therapeutic shoes directly, focusing instead on their cost-effectiveness.

C. THE LEGISLATIVE MANDATE FOR THE THERAPEUTIC SHOE DEMONSTRATION

The demonstration of a Medicare therapeutic shoe benefit was mandated in 1987 only after a long period of debate and study. This section describes the history that led up to the enactment of the demonstration and then describes the enabling legislation. The section concludes with a description of the 1989 legislation that amended the 1987 legislation.

1. Legislative History

In view of the potential benefits of therapeutic shoes for individuals at risk for severe diabetic foot disease, continuing debate has occurred about the value of adding a therapeutic shoe benefit to the Medicare program.[2]

Under the Omnibus Budget Reconciliation Act of 1980, Congress mandated a comprehensive study of methods for providing coverage for therapeutic shoes under the Medicare Part B program, as well as recommendations about legislative coverage pertaining to utilization, cost control, quality of care, and equitable and efficient administration. The Department of Health and Human Services submitted a Report to Congress in 1981. Young (1981) summarized this report, which described a design for a Medicare shoe benefit and discussed the payment and implementation issues that would need to be addressed in order to provide this benefit. The report recommended against implementing the benefit for two principle reasons.

1. The Health Care Financing Administration (HCFA) estimated that the therapeutic shoe benefit would increase Medicare Part B program costs by $85 million in fiscal year 1982.

2. HCFA believed that it would be difficult to design a benefit package that would target the individuals with greatest need. Consequently, Medicare Part B coverage for therapeutic shoes would also be extended to:

   - those who could presently afford to purchase therapeutic shoes;

[2]Currently, therapeutic shoes may be covered only if attached to an orthotic or prosthetic device.

- those who would not need therapeutic shoes to protect against increasing disability or serious medical complications; and

- those for whom less expensive foot care treatments would be suitable.

In 1985, a new bill was introduced into Congress to provide Medicare coverage for therapeutic shoes for individuals at risk for severe diabetic foot disease. The American Diabetes Association (ADA) prepared a background paper that estimated the potential cost impacts of this additional benefit. The ADA estimated that if 20 percent of amputations were averted because patients with severe diabetic foot disease used therapeutic shoes, the net annual savings to Medicare would be approximately $2.[illegible] million. Similarly, if 40 percent of amputations were averted, the potential annual savings to Medicare would be as high as $23.6 million.[3] However, the 1985 legislative initiative to add coverage of therapeutic shoes to Medicare Part B was not passed.

2 OBRA 1987

The value of a therapeutic shoe benefit to the diabetic Medicare population continued to be of interest to the Congress, the ADA, and other organizations concerned with preventing severe

[3]These estimated cost savings are probably high because the ADA study, while taking into account the costs of the expanded coverage and the avoided costs of amputations, failed to consider whether potential beneficiaries may have already obtained therapeutic shoes and, consequently, would not be affected clinically by the new coverage. The ADA study also did not recognize that the requirement of a comprehensive diabetic care plan to support the therapeutic shoe benefit would have additional costs for the Medicare program. The present demonstration is designed to measure all of these costs so that they may be included in estimates of the overall net cost impacts of the therapeutic shoe benefit.

foot diseases and amputations. The House and the Senate developed comparable bills in 1987 that would provide therapeutic shoes to a specified target group of diabetic Medicare beneficiaries under a demonstration. Agreement on coverage, benefit limitations, and demonstration dates was reached in conference. The Congress mandated a demonstration of the therapeutic shoe demonstration benefit under OBRA 1987 (P.L. 100-203, Section 4072).

The purpose of the demonstration is to determine the costs of offering a therapeutic shoe benefit under Medicare Part B and the savings that may be achieved by reducing amputations and other treatment that would have taken place without the therapeutic shoe benefit.

The OBRA 1987 legislation specified the diagnoses, medical history, and diabetic care that must be present for patients to qualify for the therapeutic shoe benefit, in order to target the benefit to those who have the greatest need and will benefit most from therapeutic shoes:

> ". . . the individual has peripheral neuropathy with evidence of callus formation, a history of pre-ulcerative calluses, a history of previous ulceration, foot deformity, or previous amputation, or poor circulation, and. . . the individual needs such shoes under a comprehensive plan of care related to the individual's diabetic condition . . . ."

In addition, the legislation specified that payment under the demonstration be restricted to one pair of shoes per calendar year, and that the amount paid be limited to $300 for custom-molded shoes and $150 for depth-inlay shoes with inserts (subject to annual price increases). Finally, the law described the types of physicians and shoe suppliers who may participate:

> ". . . the physician who is managing the individual's diabetic condition documents [the clinical conditions] . . . and certifies [the individual's need for therapeutic shoes] . . . the particular type of shoes are prescribed by a podiatrist or other qualified physician (as established by the Secretary); and the shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary) who is not the [managing] physician (unless the Secretary finds that the physician is the only such qualified individual in the area). . . ."

Congress specified that the demonstration operate initially for 2 years. This report on the cost-effectiveness of the demonstration is to be submitted to Congress by October 1, 1990. If the report establishes that the benefit is cost-effective, the demonstration will cease and the shoe benefit will be introduced on November 1, 1990. If the report does not establish the cost-effectiveness of the demonstration benefit, the demonstration will be continued for another 24 months. In that event, a final Report to Congress will be due by April 1, 1993. If the evaluation does not find net cost increases, the benefit will become effective 1 month later. If the benefit increases net costs, the coverage will not be introduced.

3. OBRA 1989

In November 1989, Congress amended the demonstration benefit in OBRA 1989 (P.L. 101-239). In addition to the shoes and inserts covered by the OBRA 1987 legislation, the benefit was expanded to include two pairs of replacement inserts per year (for either type of shoe) or shoe modifications that may be substituted for one or both pairs of replacement inserts.

This amendment was designed to address two concerns of the clinical community: that the clinical effectiveness of shoe inserts declines with wear (and thus that the benefits of the shoes would be lost if the patients did not replace their inserts regularly and that, in the absence of coverage of modifications to depth-inlay shoes, an unnecessarily large number of patients would be prescribed the more expensive custom-molded shoes (because special modifications can be built into these shoes at no additional cost). High rates of prescriptions for custom-molded shoes could have two undesirable effects: lower compliance by patients due to the appearance of the shoes and higher costs than necessary. By allowing the depth-inlay shoes to be modified, these adverse outcomes would be ameliorated, and the demonstration would be more likely to yield findings of cost savings.

D. OUTLINE OF THE REPORT

Chapter II describes the demonstration and evaluation design, the implementation of the demonstration, including a detailed discussion of the benefit and how it works, and the number of participants. Chapter III describes what is known about persons

with severe diabetic foot disease, and what is known about the characteristics of the participants in the Medicare therapeutic shoe demonstration, and their implications for its cost-effectiveness. Chapter IV describes conclusions concerning cost-effectiveness.

II. EVALUATION DESIGN, DEMONSTRATION DESIGN, AND IMPLEMENTATION

A. INTRODUCTION

This chapter describes key features of the demonstration design, the evaluation design, how the demonstration was implemented, the procedures for participants to receive the shoe benefit, and the participation rates to date. The goal of the demonstration is to provide Medicare Part B coverage for therapeutic shoes to eligible patients whereby the cost-effectiveness of the benefit can be evaluated. To receive the benefit, a patient must visit a physician, be found eligible, and send in an application form completed and signed by both parties. The demonstration contractor, Mathematica Policy Research, Inc., randomly assigns patients to enter a covered or a noncovered group and mails authorization for coverage to the covered group. The reason for the random assignment of beneficiaries is discussed in Section C of this chapter. The covered patients visit a shoe supplier authorized to provide shoes in the demonstration, who fits the shoes and bills Medicare. This process is summarized in Figure II.1.

1. Key Terms Defined

A Medicare beneficiary is eligible for the demonstration if he or she fulfills both the clinical criteria (as specified in the legislation) and the operational criteria required by the demonstration. A covered beneficiary is one who applies for and is assigned to receive the benefit.

FIGURE II.1

OVERVIEW OF THE DEMONSTRATION PROCESS

	HCFA and Demonstration Contractor	Physicians	Patients	Shoe Suppliers
1. Notification & Participation Decisions	Send Materials	Request & Receive Enrollment Forms	Receive Letter	Complete Supplier Agreement Receive Supplier Manual and Executed Agreement
2. Enrollment	Completed Forms Received & Processed ←	Certify and Prescribe ←	Visit Physician; Sign Informed Consent	
3. Randomizing	Send Payment Authorization →			
4. Shoe Supply			Visit Shoe Supplier for Fitting →	Fit Shoes
5. Claims/ Reimbursement	←			File Claim → Receive Reimbursement

A participating physician is one who enrolls a patient in the demonstration by certifying the patient's clinical eligibility and/or prescribing therapeutic shoes for the patient. Physicians must either manage the Medicare beneficiary's diabetic condition or be a podiatrist or other physician qualified to prescribe therapeutic shoes.

Only authorized shoe suppliers may receive Medicare Part B payment for supplying therapeutic shoes under the demonstration. Four types of professionals are eligible to become authorized shoe suppliers in the demonstration: doctors of podiatric medicine (podiatrists), certified pedorthists, certified orthotists, and certified prosthetists. To become authorized, these professionals must apply to HCFA, stating their qualifications, the prices they will charge, and their acceptance of the assignment of benefits under the demonstration.

2. The Schedule for the Demonstration

The Medicare Therapeutic Shoe Demonstration was authorized by OBRA 1987 with an expected start date of October 1, 1988. HCFA awarded a contract to Mathematica Policy Research, Inc., on June 30, 1988, to develop the demonstration design, implement the demonstration, and evaluate the demonstration.[1] Development of the demonstration design and operational planning for the

[1]The contract was awarded to Mathematica Policy Research, Inc., under contract number HCFA 500-87-0028-9.

implementation of the demonstration occurred during the subsequent 13 months.

An advisory panel comprised of noted clinicians with expertise in the areas of diabetic foot care and the utilization of therapeutic shoes was convened by the contractor (See Appendix B). The advisory panel provided advice on the most appropriate design features that would adequately address the congressional intent of the law and assisted in developing and simplifying procedures for providers participating in the demonstration. A preliminary demonstration design and basic operational protocol was developed. The advisory panel reviewed all major documents to be used in the implementation of the demonstration and provided comments on these reports.

Consultation and review of the demonstration design with professional societies and industry representatives was implemented during this phase. Contacts were made with the ADA, the American Podiatric Medical Association, the Prescription Footwear Association, the American Board of Certified Orthotists and Prosthetists, and the American Academy of Orthopedic Surgeons. A series of telephone and written contacts as well as a meeting with representatives of the interested groups occurred. The operational protocol and demonstration design report were finalized after comments from the above mentioned groups were received.

A prescription form was developed and submitted for the Office of Management and Budget's clearance in November 1988.

Procedures and materials for notifying beneficiaries, physicians, and potential shoe suppliers were developed with the participation of interested professional societies and the advisory panel. Arrangements were made with Medicare carriers to provide mailing labels for the demonstration notifications. The notifications were finalized and mailed to beneficiaries, physicians, and shoe suppliers.

A claims processing system for the demonstration was developed with HCFA serving as the demonstration carrier.

The demonstration was implemented in California, Florida, and New York on August 1, 1989.

Under the OBRA 1987 legislation, the therapeutic shoe benefit is available until at least October 1, 1990. If the therapeutic shoe benefit is determined to be cost-effective by this date, the demonstration will end, and the therapeutic shoe coverage will become a permanent part of the Medicare program. If the benefit is not found to be cost-effective by this date, OBRA 1987 authorizes the demonstration to continue until October 1, 1992. A final report is due to Congress on April 1, 1993. If the demonstration does not show that the benefit is not cost-effective, the demonstration will end, and the therapeutic shoe benefit will become permanent on May 1, 1993. If the benefit is determined not to be cost-effective, the demonstration will end, and no new coverage will be introduced.

B. KEY FEATURES OF THE DEMONSTRATION PROJECT

The demonstration project was designed following the congressional mandate. This demonstration project has been of great interest to the clinicians who treat patients with severe foot disease. In order to build on the clinical expertise of this group, a clinical advisory panel was formed to help design the demonstration, and extensive consultation with professional societies has taken place.

Three aspects of the demonstration design are briefly described here: the sites selected for the program; the criteria developed for targeting patients, physicians, and shoe suppliers; and the process by which patients acquire therapeutic shoes.

1. Location

The demonstration project was implemented statewide in California, Florida, and New York on August 1, 1989. For purely operational reasons, it was preferable that the demonstration operate statewide rather than in substate areas. Too many boundary issues were anticipated if patient eligibility was limited to selected counties or metropolitan areas within a State.

The evaluation requires a sample of 27,400 patients, half of whom will be eligible for therapeutic shoe reimbursement, in order to test whether the shoe benefit is cost-effective. (See

Section C of this chapter for an explanation of the sample size requirements.) Given this sample size, and the budget limitations that precluded dealing with a large number of States, a small number of large States was preferred.

Since States with high proportions of at-risk patients would be more likely to have a sufficient number of Medicare beneficiaries at risk of severe diabetic foot disease, and since access to the benefit required a sufficient number of physicians and shoe suppliers, the 20 largest States were ranked according to several measures that reflect these factors. States were ranked according to degree of urbanization, disproportionately low incomes, proportions of Black or Hispanic populations, and relative concentrations of physicians and shoe suppliers. In addition, the level of Medicare beneficiary enrollment in Health Maintenance Organizations (HMO) was reviewed, since the evaluation could not include HMO enrollees. The six highest-ranking States were New York, California, New Jersey, Florida, Illinois, and Texas. The three demonstration States were selected to represent three areas: the Northeast, the West, and the South.

2. Criteria for Participation: Patients, Physicians, and Shoe Suppliers

The OBRA 1987 legislation mandated certain requirements for the participation of patients, physicians, and shoe suppliers. Section D of this chapter describes in detail how the legislated specifications were implemented as operational criteria.

Patients must meet clinical eligibility criteria and have Medicare Part B coverage. They must also reside in a demonstration site and not be enrolled in a Medicare HMO (for reasons associated with the data needs of the evaluation).[2]

Physicians play two roles in the demonstration: they certify the clinical eligibility of patients, and they prescribe the therapeutic shoes. Those physicians who are managing the systemic diabetic condition may certify clinical eligibility. Any physician who is willing to prescribe therapeutic shoes may do so.

Shoe suppliers must be qualified to fit shoes to the diabetic foot. Because formal qualifications imply at least a minimum level of skill, professional certification was adopted for each profession deemed trained to fit therapeutic shoes.

3. The Process of Acquiring Therapeutic Shoes

Demonstration operations were designed to be as simple as possible given the many entities that would be involved in providing shoes and given that data were required for the

[2]Because payment to HMOs is capitated rather than on the basis of services furnished, HCFA does not require HMOs to submit claims for all services furnished to enrolled members.

mandated evaluation. The steps that a Medicare beneficiary must follow to receive a pair of therapeutic shoes and be paid are as follows.

1. The beneficiary visits the physician who is treating his or her diabetes.

2. The physician certifies that the beneficiary is eligible and either prescribes shoes or refers the beneficiary to another physician who prescribes the shoes. The physician gives the beneficiary the completed application form.

3. The beneficiary signs an informed consent form and mails the application form to the demonstration contractor.

4. The demonstration contractor checks eligibility and assigns the beneficiary randomly to either a covered or noncovered group. Covered beneficiaries are sent payment authorization, instructions, and a list of authorized shoe suppliers.

5. The covered beneficiary selects and visits a supplier for shoe fitting.

6. The supplier submits a claim to HCFA and is paid.

C. THE EVALUATION DESIGN

The research objective is to generate accurate estimates of the Medicare costs for the treatment of diabetic foot disease and to assess whether these costs are higher, lower, or the same as the costs of providing the therapeutic shoe benefit following the congressionally mandated demonstration criteria.[3] The goal is to estimate as closely as possible what the net costs or savings would be if the therapeutic shoe benefit were implemented

[3]The evaluation will also make estimates of Medicaid costs, taking into consideration the rate of dual Medicare/Medicaid eligibility, program costs for therapeutic shoes with and without the demonstration, and administrative costs.

nationally. The research design was developed with this primary objective in mind, but subject to the budget constraints of the demonstration and evaluation contract and the time limits imposed by the legislation.

The key issues addressed and the decisions made in selecting an evaluation design were: whether to use an experimental or a quasi-experimental design; how the groups to be compared would be identified; the sample sizes that were required to measure cost-effectiveness if it existed; and the analytic approaches to be used to measure cost-effectiveness. The key features of the evaluation design selected are as follows.

1. Both experimental and quasi-experimental designs are included in the evaluation.

2. There are two key approaches for defining the analysis groups for the evaluation.

   - Under the experimental design, eligible applicants in the demonstration States are assigned randomly to treatment and control groups, after physicians have certified eligibility.

   - Under the quasi-experimental design, a comparison group is selected from other areas than the demonstration States for comparison with beneficiaries in the demonstration States who receive the benefit. The two analysis groups will be identified from Medicare claims data.

3. Samples of 13,700 treatment group and 13,700 control group members will be required for the experimental design and a comparable number for the quasi-experimental design.

4. Medicare claims history data will be used to measure costs after assignment to the analytical groups.

5. Cost-effectiveness will be estimated using regression analysis techniques to compare the analytical groups.

1. The Choice of Design

Experimental (randomized) evaluation designs are generally preferred to quasi-experimental designs, because any differences in outcomes between treatment and control groups can be attributed to the intervention (the therapeutic shoe benefit) with reasonable certainty. In a quasi-experimental design, by contrast, there must always be some doubt about whether differences (or lack of differences) in outcomes are due to unmeasurable, pre-existing differences between the groups being compared. Thus, a randomized design meets the research objective to maximize the accuracy of the estimated impacts. As discussed below, there were also operational reasons for selecting a randomized design and research reasons for supplementing the randomized design with a quasi-experimental design.

The targeting of the sample to be assigned to the treatment and control groups was straightforward because it could build from the requirements of the legislation. The legislation mandated that the eligibility of demonstration beneficiaries be certified by a physician. By assigning demonstration applicants randomly to the covered (treatment) or noncovered (control) groups immediately after the certification had taken place, we were assured of an appropriately targeted group for the analysis that would also maximize the probability of finding impacts if they occur.[4]

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[4]The process by which beneficiaries and physicians were targeted to apply for the therapeutic shoe benefit is described in Section E of this chapter.

Therefore, we selected an experimental design in which half of the eligible applicants are assigned randomly to the treatment group and are offered Medicare Part B coverage for therapeutic shoes and half are not offered the coverage.[5]

The demonstration plans to enroll about 27,400 beneficiaries, half in the treatment and half in the control group. A sample of this size will be sufficient to detect a 6 percent impact on expenditures with 80 percent power.[6] If we assume that only 25 percent of the eligible sample will enroll in the demonstration, then the demonstration required States with a total of 110,000 eligible Medicare beneficiaries (25 percent of 110,000 is 27,500); thus, only States with large numbers of eligible Medicare beneficiaries could be considered for the demonstration.

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[5]Alternative ways to develop a randomly assigned group of patients were considered. For example, we could have randomized patients on the basis of information from their Medicare claims. We also considered basing the random assignment of patients on the randomization of physicians. Geographic regions within a State could also have been assigned randomly to treatment and control status, with all patients within an area assigned to the area status. Because operational difficulties were associated with all of these approaches, and because "gaming" by participants was a risk with each of them, we ruled out these alternatives.

[6]If we are unable to enroll the planned sample, we may not be able to establish the statistical significance of any cost changes that result from the demonstration benefit.

There are drawbacks to the randomized design. Included among them is the potential resistance of physicians to a design in which only a portion of their patients receive coverage for the shoes that they prescribe. This could affect enrollment into the demonstration if physicians prefer not to complete the demonstration application forms because only half of their patients would likely receive the coverage.[7] A problem also exists if the demonstration influences the behavior of the control group by educating them and their physicians about proper foot care and the use of therapeutic shoes. In such a case, the full impact of the benefit might not be measured, and the impact of therapeutic shoes on Medicare costs might thus be underestimated. The likelihood of this outcome would be greater if the groups who are compared lived in the same area and saw the same physicians (as is the case with the experimental design for the basic analysis). The extent of this potential "educational" effect is not known, but, since it was a potential threat to the validity of the findings, we sought to measure its effect by

[7]The demonstration has encountered resistance to participating from some physicians who have expressed concerns about the ethics of random assignment of beneficiaries to covered and noncovered groups.

augmenting the experimental design with a quasi-experimental approach in which a comparison group drawn from other States will be compared with the group who receives the benefit.[8]

Although the quasi-experimental comparison group design addresses the problems associated with an educational effect, it has a number of disadvantages. The main disadvantage of a quasi-experimental design is that there will always be doubt about whether differences (or the lack of differences) in outcomes between treatment and comparison groups are due to pre-existing and unmeasurable differences between the groups. Another major problem with this design is an operational one associated with identifying the comparison group, since no list of persons with or at risk for severe diabetic foot disease exists.

Two distinct approaches for identifying the comparison group were possible: either physician certification could be used to identify the comparison group members (that is, using the process followed for the treatment group) or the comparison group could be defined from Medicare claims histories. Clearly, physician certification was the better method for targeting and defining

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[8]While the clinicians with whom this issue was discussed felt that an educational effect might occur, they felt that it would likely be offset by the fact that patients do not like to wear therapeutic shoes, and thus the numbers of control group patients who would purchase the shoes on their own would be small.

Since the random assignment only disburses payment for the shoes and does not forbid patients in the control group (who do not receive payment for shoes) from obtaining therapeutic shoes on their own, a survey of control group patients to ascertain whether they purchased the shoes independently is planned as part of the evaluation.

the analytical groups, but it seemed likely that few physicians in comparison States in which no benefit was being offered would be willing to complete certification forms for all their eligible patients. Therefore, claims histories will be used to identify the target groups for the quasi-experimental analysis. Doing so means that unmeasurable differences between the two analysis groups could be quite large, casting more doubt on any findings than if good eligibility certification data were available. This was a further reason for considering the quasi-experimental design less desirable on its own than in combination with the experimental design.

Under the quasi-experimental design, a treatment group will be identified from both the demonstration beneficiaries and persons not participating in the demonstration but residing in the demonstration States. A comparison group will be chosen from other States. The two groups will be selected on the basis of their Medicare claims history. A group of Diagnosis Related Groups (DRGs) and diagnostic codes has been selected which are believed to indicate the target group (see the related discussion in Chapter III). The Medicare claims histories of the demonstration's participants will be reviewed late in the evaluation to refine the proposed screening criteria for identifying the comparison group.

Comparison group States will be selected to match the demonstration States as closely as possible along a variety of demographic, economic, and geographic factors.

2. The Cost-Effectiveness Analysis

Consistent with the OBRA 1987 statute, cost-effectiveness will focus on budget neutrality from the perspective of aggregate Federal and State governments' costs. These costs will include Medicare-covered visits to physicians (including podiatrists) for regular care and shoe prescriptions, Medicare costs for amputations and inpatient procedures for diabetic foot disease, Medicaid payment of deductibles, and copayments for these items and services.[9]

The evaluation will provide two ways to estimate the impact of the therapeutic shoe benefit on Government costs. First, the impact of the demonstration benefit will be estimated on the basis of the experimental design. The Medicare costs of the noncovered (control) group for foot care will provide the estimated costs in the absence of the benefit. The costs of the covered (treatment) group will provide the estimated costs of a

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[9]California and New York cover therapeutic shoes under their Medicaid programs, although the administrative requirements in New York result in relatively few claims for therapeutic shoes being paid. Florida does not cover therapeutic shoes. Under the demonstration, the Florida and California Medicaid programs will pay the Medicare coinsurance and deductibles of qualified beneficiaries who are entitled to both Medicare and Medicaid. In California, the Medicaid program costs of dually eligible Medicaid beneficiaries may be reduced (if Medicaid patients now receive reimbursement through Medicare for services they would otherwise have received through Medicaid) while in Florida, Medicaid program service costs for shoes will be increased. The evaluation of Medicaid costs under the demonstration will be limited to Medicaid payment of Medicare deductibles and copayments for demonstration items and services. The evaluation will not cover the total shift of costs between title XVIII and title XIX.

nationally available benefit. The difference in these two cost estimates is the net cost of the shoe benefit. If the costs to the treatment group are significantly higher than the costs to the control group, then the benefit will not be cost-effective. Nevertheless, if the demonstration increases the use of therapeutic shoes by the control group, their costs might be lower than they would have incurred in the true absence of the benefit, and the higher costs of the treatment group would be relatively over-estimated. (Alternatively, if the treatment group costs were lower, they would be relatively underestimated.)

Second, the cost estimates for the treatment group in the demonstration States will be compared with the cost estimates of similar persons in comparison sites in which no education occurred (the gross cost difference will be estimated). If the costs of the treatment group are significantly higher, then the benefit will not be cost-effective. The evaluation of the demonstration will rely on comparisons of means and regression techniques to estimate the impact of the shoe coverage on costs and services used.

Data sources for the analyses will include Medicare claims data, the shoe claims under the demonstration, the demonstration application form that describes clinical characteristics (see Appendix A), estimates of the dual Medicare and Medicaid entitlement of demonstration participants, and the Medicare coinsurance and deductible amounts that are paid by the Medicaid program.

D. THE DEMONSTRATION BENEFIT

1. Definition of the Benefit

The therapeutic shoe benefit authorized by OBRA 1987 provides Medicare Part B coverage for therapeutic shoes and inserts for eligible Medicare beneficiaries. OBRA 1989 amended the therapeutic shoe benefit to include coverage for two pairs of replacement inserts or modifications to therapeutic shoes equal in value to the replacement inserts. Therapeutic shoes are designed to provide protection for insensate feet and altered support for feet that are changing in shape and for which normal shoes provide inadequate support. Two types of therapeutic shoes are covered under the demonstration.

- Depth-inlay shoes are therapeutic shoes that provide additional depth in order to accommodate a removable insert (also called an "inlay"). These shoes must have some type of shoe closure; slip-on styles are not covered under the demonstration. The demonstration benefit includes one pair of removable inserts with the depth-inlay shoes.

- Custom-molded shoes are shoes molded from a positive cast of the patient's foot. These shoes must also have some type of shoe closure; the demonstration does not cover slip-on styles. A pair of custom-molded shoes may include inserts and special modifications that are built into the shoes as they are constructed (for example, elevations, wedges, flares, and rocker soles).

Covered beneficiaries may receive one pair of therapeutic shoes per year. Covered beneficiaries may also receive two pairs of replacement inserts per year or additional modifications to their therapeutic shoes.

- Inserts for therapeutic shoes are total-contact, customized, multiple-density, removable inlays, molded directly to the patient's feet or from a positive cast of patient's feet. Examples of acceptable thermomoldable materials for inserts are polyethylene foams such as Plastazote, Pelite, and Aliplast. Examples of acceptable nonthermomoldable materials for inserts are Spenco, Sorbothane, STS, PPT, PQ, and leather.

Noncovered services include custom-made shoes, therapeutic shoes intended to be temporary (for example, healing sandals), and repairs.

2. Patient Eligibility Criteria

Clinical eligibility criteria for the demonstration include a diagnosis of diabetes and one or more of the following conditions in one or both feet:[10]

- previous amputation of the foot or part of the foot;
- foot deformity with a potential for ulceration;
- callus formation or a history of callus formation with peripheral neuropathy;
- a history of previous foot ulceration; or
- poor circulation.

Beneficiaries must also be under a comprehensive plan for care for the diabetic condition.

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[10]These criteria diverge slightly from the wording in the legislation to reflect the recommendations of the demonstration's clinical advisory panel (see Appendix B). The panel was concerned that "foot deformity," for example, was too broad a category and could result in the enrollment of beneficiaries who would not benefit from the shoes.

Operational eligibility criteria include current Medicare Part B coverage, residence in one of the demonstration sites, and nonmembership in a Medicare HMO. Medicare Part B coverage is required because therapeutic shoes are covered as a Medicare Part B benefit. Medicare HMO members are excluded for research purposes because it is not possible to collect the claims data from HMOs that are necessary for testing cost-effectiveness.

3. Shoe Prices and the Assignment of Benefits

The statutorily mandated maximum allowed prices for furnishing therapeutic shoes under the demonstration were set in the legislation, with a provision that they be adjusted annually according to the price index for durable medical equipment. The 1990 prices are as follows:

- Custom-molded shoes - $305;
- Depth-inlay shoes - $102; and
- Inserts supplied with depth-inlay shoes - $51.

The price for replacement inserts is also $51 per pair. The price of modifications to therapeutic shoes may be up to the price of the replacement inserts for the shoes.

Authorized shoe suppliers in the demonstration are required to accept assignment of benefits for furnishing therapeutic shoes to patients in the demonstration (that is, they agree to accept the maximum allowed price, or a lower price, as the full charge for the service). Authorized shoe suppliers may receive payment from Medicare Part B equal to 80 percent of the lesser of

their agreed rate (the maximum allowed or a lower price contracted for by the shoe supplier) and the actual charge for service, both subject to the patient's Medicare annual deductible charge. The patient is responsible for the remaining 20 percent co-payment plus any outstanding Medicare annual deductible. The total amount received by the authorized shoe supplier cannot exceed the maximum allowed rate.

The Medicaid programs of two of the demonstration States are also participating in the demonstration.[11] Medicaid will pay the 20 percent copayment and Medicare annual deductible for dually eligible covered beneficiaries.

E. NOTIFICATION OF PARTICIPANTS

The notification activities were designed to maximize participation in the demonstration by providing information to three types of participants: Medicare beneficiaries; physicians and shoe suppliers; and to associations of interested persons.

1. Notification of Medicare Beneficiaries

It was not possible to identify all clinically eligible individuals, nor was it feasible (or advisable) to notify all Medicare Part B beneficiaries. Therefore, using Medicare Part A hospital inpatient claims records for 1987 and 1988, the demonstration contractor identified beneficiaries in demonstration States who had a hospital stay for a diabetic foot

[11]The New York Medicaid program has decided not to participate in the demonstration.

problem in recent years. Notifications were mailed to these 43,064 Medicare beneficiaries in July 1989. These notifications explained the purpose and limitations of the benefit, and instructed the patients to ask their physician to enroll them at their next visit. These 43,064 beneficiaries were distributed across the three demonstration States as follows: California, 15,495; Florida, 10,985; and New York, 16,584.

2. Notification of Physicians

The Medicare carriers in the three demonstration States identified and provided labels for physicians in the specialties most likely to provide care for diabetic patients:

- general and family practitioners;
- internists (including endocrinologists);
- orthopedic surgeons;
- vascular and general surgeons; and
- podiatrists.

The notification to physicians included an introductory letter and a return postcard. The letter briefly described the demonstration benefit, explained how patients would apply for the therapeutic shoe coverage, and described the random assignment of patients to treatment and control groups. Physicians who were interested in receiving more information and materials for enrolling patients were instructed to complete and return the enclosed postcard.

Table II.1 shows the volume of the mailing and how the physicians were distributed across States and specialties. The total numbers and distribution across specialties are similar to those for the population of patient care physicians in the three demonstration States.[12] Most (64 percent) of the physicians were internists, general practitioners, and family practitioners. This is the group that sees between 80 and 90 percent of diabetic patients. Orthopedic, general, and vascular surgeons (specialties likely to provide surgical care for severe diabetic foot conditions) comprised about 13 percent of the physicians notified. Ten percent of the physicians notified were podiatrists, who are foot and ankle specialists.

[12]This finding is based on a comparison with published American Medical Association data for 1987. However, some duplication across carriers may exist in New York and California, where there are multiple carriers.

TABLE II.1

FIRST NOTIFICATIONS TO PHYSICIANS

	State			Total	
	California	Florida	New York	Number	Percent
General and Family Practitioners	20.0%	45.2%	29.3%	16,741	29.8%
Internal Medicine (including Endocrinologists)	23.6%	30.2%	45.9%	19,071	33.9%
Orthopedic Surgeons	5.9%	7.2%	6.9%	3,717	6.6%
General & Vascular Surgeons	5.5%	11.8%	4.6%	3,772	6.7%
Podiatrists	10.3%	5.4%	12.9%	5,703	10.1%
Unspecified California	34.6%	0.0%	0.0%	7,126	12.7%
Hospitals	0.0%	0.1%	0.4%	106	0.2%
Total	100.0%	100.0%	100.0%		100.0%
Total Number	20,566	13,759	21,911	56,236[a]	
Number of Unspecified Duplicates	--	--	--	5,222	
Grand Total Numbers				61,458	

SOURCE: Magnetic tapes and labels provided by:

TransAmerica Occidental Life Insurance Company
Blue Shield of California
Blue Shield of Florida
Blue Shield of Western New York
Empire Blue Cross
Group Health Insurance

[a] Because one of the California carriers provided only mailing labels, we are not able to obtain a complete distribution of physician specialties for California. In addition, carriers who provided both mailing labels and a magnetic tape included many more listings and/or duplicates in the set of mailing labels. One New York carrier estimated that the Medicare file contained about 4,000 duplicates. We know that the total number of items mailed was 61,458.

NOTE: Percentages may not add up correctly due to rounding.

3. Notification of Shoe Suppliers

The universe of members of four professional groups was identified and sent a mailing in June 1989.[13] Table II.2 shows the distribution of the types of professionals who were sent the shoe supplier notification. Podiatrists comprised 83 percent of the universe of professionals notified. Prosthetists, orthotists, and orthotists/prosthetists together comprised almost 15 percent of the total population of shoe suppliers. Although pedorthists specialize in fitting therapeutic shoes, at 2 percent of the universe of professionals notified, they are the smallest professional group.

4. Notification of and Coordination with Professional Associations

In addition to notifying individual physicians about the demonstration, the demonstration contractor also notified national and State physician professional organizations, local chapters of the ADA, hospitals and clinics with special diabetes treatment or education programs, and carriers in the

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[13]Mailing labels for podiatrists were provided by the Medicare carriers in the demonstration States. The Board for Certification in Pedorthics (which certifies pedorthists) and the American Board for Certification (ABC) (which certifies orthotists and prosthetists) provided mailing labels for certified professionals in the demonstration States. In addition, the demonstration contractor obtained mailing labels from the Prescription Footwear Association many of whose members would be qualified. In September 1989, the demonstration contractor received mailing labels from the New York Board of Certified Orthotists (NYBCO). Orthotists in New York who are certified by NYBCO have equal standing with orthotists certified by ABC and are eligible to receive reimbursement for Medicare Part B services in New York State.

TABLE II.2

POTENTIAL SHOE SUPPLIERS BY PROFESSION WHO WERE NOTIFIED ABOUT THE DEMONSTRATION

	State			Total	
	California	Florida	New York	Number	Percent
Pedorthist (C.Ped)	1.0%	3.2%	2.3%	126	2.0%
Prosthetist (C.P.)	4.9%	6.4%	1.9%	227	3.6%
Orthotists and Orthotist/Prosthetist (C.O. and C.P.O)	10.4%	10.9%	11.5%	695	11.0%
Podiatrist (D.P.M.)	83.7%	79.5%	84.4%	5,264	83.4%
Total	100.0%	100.0%	100.0%		100.0%
Total Number	2,231	942	3,139	6,312	

SOURCES. TransAmerica Occidental Life Insurance Company
Blue Shield of California
Blue Shield of Florida
Blue Shield of Western New York
Empire Blue Cross
Group Health Insurance
The Board of Certification in Pedorthics
American Board of Certification in Orthotics and Prosthetics
New York Board of Certified Orthotists

NOTE: The number of podiatrists receiving supplier notifications is fewer than the number receiving physician notifications. This is because the number of mailing labels received from the carriers was fewer for this notification.

NOTE: Percentages may not add up correctly due to rounding.

demonstration States. These organizations were mailed notification materials and a short article about the demonstration for inclusion in newsletters to members. Table II.3 lists the groups that were notified. Several of the associations listed in Table II.3 also played a role in developing the demonstration materials, including the notification letters and the instructions to participating patients, physicians, and suppliers. The demonstration's advisory panel also reviewed all these materials. The panel members are listed in Appendix B.

Articles about the demonstration have also been prepared for Diabetes Spectrum (a physician-oriented publication from the ADA), carrier newsletters to Medicare providers, and local ADA newsletters. These groups and diabetes treatment and education programs identified by local ADA offices have been sent complete patient application materials.

F. THE ENROLLMENT OF PATIENTS IN THE DEMONSTRATION

The goal is to enroll 27,400 beneficiaries who meet the eligibility criteria, to be divided evenly into a treatment (benefit receiving) group and a control group through a random assignment process. As of November 25, 1989, 1,002 beneficiaries had applied, 831 of whom were eligible.

TABLE II.3

GROUPS THAT RECEIVED DEMONSTRATION NOTIFICATION MATERIALS

American Academy of Family Physicians
American Academy of Orthopedic Surgeons
American Podiatric Medical Association
American Orthopedic Foot and Ankle Society
Endocrine Society
Society for Vascular Surgery
American Board of Family Practice
American Board of Internal Medicine
American Board of Podiatric Orthopedics
Federation of State Medical Boards of the United States
American Board for Certification in Orthotics and Prosthetics
New York Board of Certified Orthotists
Board for Certification in Pedorthics
Prescription Footwear Association
California Academy of Family Physicians
California Medical Association
California Podiatric Medical Association
Florida Academy of Family Physicians
Florida Medical Association
Florida Podiatric Medical Association
Medical Society of the State of New York
New York Academy of Family Physicians
New York Podiatric Medical Association
American Diabetes Association, National Service Center
American Diabetes Association, California Affiliation
American Diabetes Association, New York Affiliation
American Diabetes Association of Upstate New York
American Diabetes Association of Upstate New York, Syracuse Regional Chapter, Capital District Chapter, Northern New York Chapter, Rochester Regional Chapter, Plattsburgh, NY, Buffalo, NY, Binghamton, NY

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1. The Use of a Special Prescription Form

A special form, entitled the "Demonstration Certification and Prescription Form," is the patient's application for the demonstration (see Appendix A). The form includes two sections to be completed by a physician during a regular visit: certification of clinical eligibility and a prescription for therapeutic shoes; and a patient consent agreement that must be signed by the patient. The completed form is mailed to the demonstration contractor for processing.

Certification of Clinical Eligibility A physician who manages the patient's diabetic condition must use the form to certify that the patient is diabetic and has one or more severe foot conditions in at least one foot and to certify that the patient needs therapeutic shoes as part of a comprehensive plan of care for diabetes.

Prescription for Therapeutic Shoes Either the physician who manages the patient's diabetic condition or a podiatrist or another physician may write a prescription for either depth-inlay shoes with inserts or custom-molded shoes and may also write special instructions about the patient's feet or shoes. Physicians who do not know how to prescribe shoes may refer the patient to one who does (such as a podiatrist), or they may learn how to prescribe shoes by working with shoe suppliers during the demonstration.

Patient Consent Agreement The informed consent agreement states that the patient understands that the therapeutic shoe coverage is offered as a temporary benefit and that half of the eligible applicants will be chosen randomly to receive the coverage. A large-type version and Spanish translation of the patient consent agreement are provided on the back of the Demonstration Certification and Prescription Form.

2. Application Processing

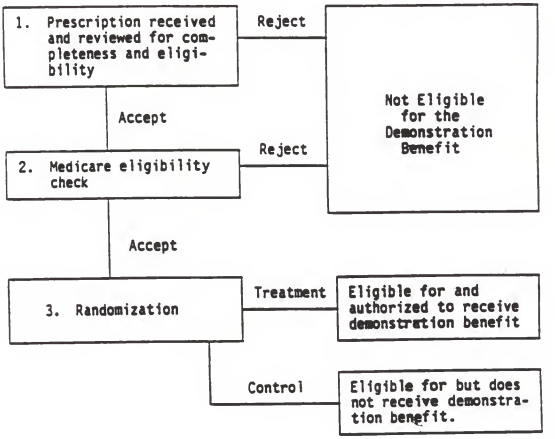
Patients' Certification and Prescription Forms are processed in three stages (see Figure II.2).

A Review for Completeness and Eligibility The forms are reviewed for completeness and eligibility. Forms that are missing key information, (e.g., a Medicare number or physician or patient signatures) are returned to the patient with a form letter to explain what is wrong. Patients are asked to correct and resubmit the form.

Medicare Eligibility Check HCFA checks Medicare records for persons with complete forms to ensure that they have current Part B coverage. The Medicare records are also checked to ensure that Medicare HMO enrollees and out-of-State residents are identified and flagged as ineligible. Ineligible applicants are informed that they are ineligible, and the reason why, and that they may resubmit a corrected form if the information is in error.

FIGURE II.2

PATIENT ENROLLMENT PROCESS



NOTE: The numbers of applicants in each category as of November 25, 1989 are shown in Table II.5.

Random Assignment Patients who are confirmed to be eligible for the demonstration benefit are assigned randomly to the treatment and control groups. Assignment is equal (50 percent to each group) and is controlled within each State.[14] Treatment group members are mailed the Certification and Prescription Form, a Payment Authorization Form for therapeutic shoes, Instructions to Medicare Beneficiaries, and a list of authorized shoe suppliers in their State. The elapsed time from the receipt of application to the mailing of the assignment information is a maximum of 7 weeks.

Control group members are mailed a letter to indicate that they have not been selected to receive payment for therapeutic shoes. Their prescription forms are attached to the letter.

Table II.4 shows the distribution of applicants, eligible applicants, and the coverage of eligible applicants by treatment and control group status and State through November 1989.

G. PHYSICIAN PARTICIPATION AND ROLE

1. Enrollment Materials

Physicians who responded to the physician notification were sent an information package that included five items:

1. Demonstration Certification and Prescription Forms (the patient application form);

[14]When two samples are drawn randomly, there should be little or no significant differences in the prevalence of the characteristics between the treatment and control groups. We tested whether this was true to be sure that randomization procedures were working. We found that the treatment and control groups were comparable based on the characteristics recorded on the demonstration certification and prescription form.

TABLE II.4

APPLICANTS TO THE MEDICARE THERAPEUTIC SHOE DEMONSTRATION BY NOVEMBER 25, 1989

	California	Florida	New York	Total
Number of Prescription Forms Received[a]	301	347	377	1,025
Number of Prescription Forms Rejected at Initial Review[b]	50	50	48	148
Number of Prescription Forms Accepted at Initial Review	251	297	329	877
Number of Ineligible Forms[c]	14	13	19	46
Number of Eligible Forms	237	284	310	831
Number of Treatments (receive coverage)	118	142	156	416
Number of Controls (do not receive coverage)	119	142	154	415

[a]Number of prescription forms received includes those accepted, rejected, corrected, re-submitted, or carried over into the following month's processing.

[b]Rejected on initial processing due to missing data or clear ineligibility.

[c]Ineligible when Medicare records are checked or previously assigned to the treatment or control group.

2. A booklet containing background information on the demonstration and detailed instructions for completing the Certification and Prescription Forms;

3. A copy of the Instructions to Medicare Beneficiaries (which is mailed to patients randomized into the treatment group);

4. A list of authorized shoe suppliers in the physician's State; and

5. A notice to clarify the physician's qualifications for certifying patient eligibility.

The first mailing of information packages was sent to 2,179 physicians at the end of July. An additional eight mailings were made through November 1989, yielding a total of 3,094 physicians. In addition, the demonstration contractor mailed information packets to other health professionals and shoe suppliers, who provide the materials to physicians.

Table II.5 shows how the physicians who have requested information packets are distributed across specialties. In all three States, about 40 percent of the physicians who requested materials are podiatrists. About 30 percent are physicians who are likely to be the physicians who manage the patients' diabetes (i.e., general and family practitioners and internists). Table II.5 also shows the response rate of each specialty. The number of podiatrists who requested information packages was nearly one-fourth of the number of podiatrists notified. Orthopedic surgeons ranked second in response rate; 7 percent of those notified requested information. Among the other specialties, 3 percent or fewer requested packages.

TABLE II.5

RESPONSE RATES TO FIRST NOTIFICATION
BY PHYSICIAN SPECIALTY AND BY STATE:
PHYSICIANS SENT INFORMATION PACKAGE BY NOVEMBER 25, 1989

	State			Total		Responding Physicians as a percentage of Those Notified
	California	Florida	New York	Number	Percent	
General and Family Practitioners	15.5%	18.6%	7.0%	402	12.9%	2.4%
Internal Medicine, including:						
Endocrinologists	17.2%	14.9%	21.0%	563	18.2%	3.0%
Orthopedic Surgeons	9.3%	10.0%	5.7%	251	8.1%	6.8%
General and Vascular Surgeons	1.9%	5.2%	2.0%	83	2.7%	2.2%
Podiatrists	42.1%	36.1%	47.6%	1,327	42.9%	23.3%
Other and Unspecified	10.9%	12.4%	15.8%	405	13.1%	--
Medical Groups and Hospitals	3.1%	2.8%	0.9%	68	2.2%	--
Total	100.0%	100.0%	100.0%		100.0%	--
Total Number Requesting Information	1,178	717	1,199	3,094		--

NOTE: This table shows the distribution of physicians by specialty within each state and in total who responded to the first notification and requested the information package.

NOTE: Percentages may not add up correctly due to rounding.

H. AUTHORIZED SHOE SUPPLIERS FOR THE DEMONSTRATION

Following the legislative mandate, the demonstration has specified that the following professionals may fit and supply therapeutic shoes: doctors of podiatric medicine (podiatrists) and certified prosthetists; pedorthists; and orthotists.[15] In addition, shoe suppliers must be authorized by HCFA to supply the shoes and to be paid. Authorization takes place as follows.

The demonstration requires that shoe suppliers sign individual agreements. The supplier notification described above included the agreement, as well as the following:

- an introductory letter;
- information for Supplier Payment with instructions (required for claims reimbursement); and
- HHS Form No. 441 with explanation (the federally required form for Assurance of Compliance with the DHHS regulation under title VI of the Civil Rights Act of 1964).

Interested parties complete the Participating Supplier Agreements, Information for Supplier Payment, and HHS Form No. 441 and return them to the demonstration contractor. If the supplier application materials are complete and the prices requested are not greater than the legislated maximum, the agreements are forwarded to HCFA. HCFA approves and signs each Participating Supplier Agreement. The executed Agreements are returned to the suppliers.

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[15]Podiatrists may supply shoes to patients for whom they prescribed shoes, but to avoid conflict of interest, they may not certify patient eligibility and supply shoes.

Podiatrists who request special approval to both certify and fit shoes for one patient are approved only if they practice in a county that contains fewer than 10 patient care physicians.[16] Only one podiatrist has thus far received this approval. Agreements that are not approved to certify and supply shoes to the same patient are so marked by the demonstration contractor.

Authorized shoe suppliers are mailed a Shoe Supplier Manual, a Notice to Authorized Shoe Suppliers, their executed Participating Supplier Agreement, and a copy of the Physician Information Packet, including Physician Instructions, Instructions to Medicare Beneficiaries, and three Demonstration Certification and Prescription Forms. The Shoe Supplier Manual explains the patient application and demonstration billing procedures.[17] The Notice to Authorized Shoe Suppliers explains the enrollment of patients and informs suppliers that the enclosed Physician Information Packet may be distributed to physicians.[18]

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[16]The number of physicians per county is derived from Physician Characteristics and Distribution in the U.S., 1987 edition, American Medical Association, Chicago, 1988.

[17]The Medicaid program in two of the demonstration States agreed to participate in the demonstration and offer Medicaid coverage for co-payments and Medicare annual deductibles if the patient has both Medicaid coverage and demonstration coverage. Authorized shoe suppliers will make claims to Medicaid directly.

[18]By sending patient enrollment materials to shoe suppliers, the demonstration contractor hopes to reach additional physicians who use therapeutic shoes as treatment for their patients, but who did not receive or did not respond to the notification letters.

After Participating Supplier Agreements are executed by HCFA, the shoe supplier's name and address are added to the list of authorized shoe suppliers that is provided to covered beneficiaries and physicians who request information packages. Shoe suppliers may list multiple office or store locations in the supplier application, and all of these locations in demonstration States are listed.

Table II.6 shows the distribution of authorized shoe suppliers by profession. Nearly two-thirds of the authorized shoe suppliers are podiatrists, which is not surprising since podiatrists constituted 84 percent of the potential population of shoe suppliers who were mailed notifications. Although the number of responses from the other professions has been low in proportion to the number notified, the highest response rates have been among pedorthists (21 percent of those notified have signed up).

I. CONTACTS WITH PROFESSIONAL ASSOCIATIONS AND JOURNALISTS

As indicated in the discussion of notification processes, project staff have had considerable contact with some of the professional associations in designing and implementing the demonstration. Since the fall of 1988, the demonstration contractor and HCFA staff have worked with the Prescription Footwear Association, the American Podiatric Medical Association and its State affiliates, and the ADA and its affiliates. Staff have made presentations at meetings and met with association

TABLE II.6

AUTHORIZED SHOE SUPPLIERS BY SPECIALTY AS OF NOVEMBER 25, 1989

	State			Total		Percent of Those Notified
	California	Florida	New York	Number	Percent	
Pedorthist (C.Ped)	3.2%	10.0%	11.2%	27	7.9%	21.4%
Prosthetist (C.P.)	2.4%	4.2%	2.0%	10	2.9%	4.4%
Orthotists and Orthotist/ Prosthetist (C.O. and C.P.O)	11.1%	10.8%	17.4%	44	12.8%	6.3%
Podiatrist (D.P.M.)	65.1%	64.2%	62.2%	220	64.0%	4.2%
Combinations (supplier with employees of more than one specialty)	18.3%	10.8%	7.1%	43	12.5%	--
Total	100.0%	100.0%	100.0%		100.0%	--
Total Number	126	120	98		344	--
Number of Shoe Supplier Locations	192	185	137		514	--

NOTE: Percentages may not add up correctly due to rounding.

staff to clarify demonstration issues to providers, suppliers, and patients. An article was submitted to the ADA for inclusion in the physician-oriented journal Diabetes Spectrum. Numerous telephone calls have been received from magazines and newspaper journalists, as a result of which articles have appeared in Podiatry Today (a monthly trade paper), The Syracuse Post-Standard, and other papers that use Associated Press syndication.

III. WHAT WE KNOW ABOUT COST-EFFECTIVENESS OF THERAPEUTIC SHOES FOR MEDICARE BENEFICIARIES AT RISK OF SEVERE FOOT DISEASE

This chapter presents what is currently known about the cost-effectiveness of therapeutic shoes for Medicare beneficiaries at risk for severe foot disease. Because there are no followup findings from the demonstration yet, the focus in this chapter is on the factors that affect cost-effectiveness.

The chapter begins with a review of the literature on the prevalence of diabetes among Medicare beneficiaries, the prevalence of persons at risk of severe foot disease, and the prevalence of severe diabetic foot disease. The implications of these data are discussed.

The literature review is followed by a description of the diagnoses of the Medicare beneficiaries who were notified about the demonstration. Finally, the characteristics of the 831 beneficiaries enrolled in the demonstration through November 25, 1989, are described and the implications of the findings for cost-effectiveness are reviewed. The detailed data on the demonstration participants provide preliminary estimates of the prevalence of various foot problems and the use of therapeutic shoes among diabetic Medicare beneficiaries with severe foot disease. Later in the demonstration, we expect that relatively good estimates of the prevalence of foot disease and risk factors for foot disease will be developed for Medicare beneficiaries.

A discussion of the progress of the demonstration and the implications of this progress for the longer term evaluation of cost-effectiveness of the therapeutic shoe benefit is presented in Chapter IV.

A. LITERATURE REVIEW ON PREVALENCE OF SEVERE FOOT DISEASE AND ITS COMPLICATIONS

There is little documented evidence on the number of Medicare beneficiaries with diabetes, and even less evidence on the number of diabetic Medicare beneficiaries who are at risk of or have developed severe foot problems as a result of their diabetes. The lack of data was problematic in designing the demonstration and the evaluation, since the costs of avoidable foot disease and the likely universe of beneficiaries at risk were important factors in the sample size calculations and the choice of sites for the demonstration.

In this section, estimates are presented of the prevalence of diabetes, those at risk of severe foot disease, and those with severe foot disease in the Medicare population. We indicate how the estimates were derived and indicate which we consider to be the best. The estimates are summarized in Table III.1. Unless otherwise indicated, all estimates are for 1988, since that is the most recent year for which reliable population data are available. The implications of the prevalence data for reaching the demonstration's sample goals are also discussed.

TABLE III.1

ESTIMATES OF THE EXTENT OF DIABETES AND SEVERE DIABETIC FOOT DISEASE AMONG MEDICARE BENEFICIARIES

Measure	Rate Per 1,000	Total Number of Persons	Source
A. DIAGNOSED DIABETES AMONG MEDICARE BENEFICIARIES OVER 65 YEARS[a]			
1. 1979-1981			
65-74 years	87.7	1,338,000	Harris (1985)
75 years or more	89.4	785,000	
TOTAL	--	2,123,000	
2. 1988			
65-74 years	87.7	1,569,566	Extrapolations from Harris rates to U.S. census population estimates in 1988.
75 years or more	89.4	1,114,729	
		2,684,296	
3. 1983-1985			
65-74 years	97.9		Collins (1988)
75 years or more	91.8		
4. 1988			
65-74 years	97.9	1,752,116	Extrapolations from Collins estimates to U.S. Census population estimates for 1988.
75 years or more	91.8	1,144,654	
TOTAL		2,896,770	
B. SEVERE FOOT DISEASE AMONG DIABETIC MEDICARE BENEFICIARIES OVER 65 YEARS			
1. 1988	30.0	86,903	ADA, unpublished rate estimate applied to 1988 estimates of the number of Medicare beneficiaries over 65 years with diabetes.
2. 1980-82			
65-74 years	156.0		Palumbo and Melton rates of history of ulcers or sores on feet or ankles.
75 years or more	173.4		
3. 1988			
65-74 years	156.0	273,330	Palumbo and Melton rates of history of ulcers or sores on feet or ankles applied to 1988 estimates of the number of Medicare beneficiaries with diabetes.
75 years or more	173.4	198,483	
TOTAL		471,813	
4. 1988		415,148	Mathematica Policy Research estimate from Medicare claims history files and number of Medicare beneficiaries.[b]

TABLE III.1 (continued)

Measure	Rate Per 1,000	Total Number of Persons	Source
C. LOWER EXTREMITY AMPUTATION RATES AMONG DIABETIC MEDICARE BENEFICIARIES OVER 65 YEARS			
1. 1984		12,400	ADA
2. 1985		29,530	NCHS, unpublished
3. 1988	10	28,968	Most and Sinnock (1983) rate applied to 1988 estimates of Medicare diabetic population.
4. 1988		9,946	Based on Medicare claims for 1987 and estimates of number of Medicare beneficiaries for 1988.[c]

NOTE: The population of 65 years or more is used a proxy for the number of Medicare beneficiaries in this table.

[a]Very little is known about the prevalence of insulin-dependent diabetes in adults. LaPorte and Tajima in Diabetes in America, NIH, 1985.

[b]Calculated as the annual rate of hospital stays for diabetic foot disease (3.23 per 1,000 Medicare beneficiaries), multiplied by the number of Medicare beneficiaries in 1988, times four. Claims data were for California, Florida, and New York for 1986 to 1988.

[c]Claims data for California, New York, and North Carolina for 1987 were used.

1. Incidence and Prevalence of Diabetic Medicare Beneficiaries with Severe Foot Disease

a. Diabetes in Persons Over Age 65

Estimates of the prevalence rate of diagnosed diabetes from the 1979 to 1981 Health Interview Survey presented in Harris (1985) indicate that there were over 2 million aged persons with diagnosed diabetes in the United States at that time. Harris (1985) cites an 87.7 per 1,000 population rate of diagnosed diabetes among persons 65 to 74 years of age and an 89.4 per 1,000 rate among those over 75 years of age.[1] Applying these prevalence rates to 1988 Census population estimates results in an estimate of nearly 2.7 million diagnosed diabetic patients aged 65 years or more.

More recent estimates of diabetes prevalence from the 1983 to 1985 Health Interview Survey show much higher rates of diagnosed diabetes, continuing a long term trend of increases (Collins, 1988). Among persons aged 65 to 74 years, the diagnosed rate was 97.9 per 1,000, and among those 75 years and over the rate was 91.8 per 1,000. Applying these rates to the 1988 Census population estimates yields an estimate of nearly 2.9 million persons over 65 years with diabetes.

Given that rates of diagnosed diabetes are increasing over time and that the most recent population estimates are the appropriate ones to use, the best estimate of the number of diagnosed diabetic persons 65 years or more is 2.9 million. This

[1] About 95 percent of these cases are believed to be non-insulin dependent.

probably closely approximates to the number of Medicare beneficiaries aged 65 years and more with diabetes and hence constitutes the pool from which those at risk for severe foot disease will develop. This estimate, however, does not include the number of disabled Medicare beneficiaries under 65 because data on the incidence of diabetes for this group are not readily available; hence, it underestimates the pool of Medicare beneficiaries at risk of developing severe diabetic foot disease.

b. Severe Foot Disease

While clinicians generally agree on the risk factors for developing severe foot disease, and these risk factors were adopted as clinical eligibility criteria for the demonstration, there are no estimates of the number of persons at risk for severe foot disease by risk factor or in total. There are, however, a few estimates of the number of aged diabetic Medicare beneficiaries who have developed severe foot disease.

In 1986 the ADA developed a background paper that estimated that approximately 30 per 1,000 diabetic persons aged 65 and over were suffering from diabetic foot disease. There is, however, no supporting evidence in published material for this prevalence rate. Applying the ADA estimate of 30 per 1,000 diabetic persons to the estimated number of diabetic persons aged 65 years and over in 1988 (nearly 2.9 million) yields an estimate of 86,903 persons with severe foot disease.

Palumbo and Melton (1985) present data from a study of diabetic patients in Wisconsin that found that in 1980 to 1982, 156 per 1,000 persons with diabetes aged 65 to 74 and 173.4 per 1,000 persons with diabetes over age 75 have a history of ulcers or sores on the foot or ankle; i.e., they have evidence of foot disease. Applying these rates to the 1.7 million diagnosed diabetic persons in the 65 to 74 age group and the 1.1 million diabetic persons over age 75 yields an estimate of 471,813 persons 65 years or more (which is a proxy for the population of Medicare beneficiaries) with severe foot disease. This estimate is over five times larger than the ADA estimate.

An independent estimate of the percentage of Medicare beneficiaries with severe foot problems was made using data from the Medicare Automated Data Retrieval System (MADRS) for 1986, 1987, and part of 1988 for California, Florida, and New York. We determined that almost 1 percent (.97 percent) of all Medicare beneficiaries in these States had hospital stays for severe foot problems and accompanying diabetes over the period (or somewhat over .323 percent per year)[2]. Applying the annual rate to the number of Medicare enrollees in the United States in 1988 yields an estimate that nearly 104,000 beneficiaries would have had hospital stays for diabetic foot problems in a given year, but that the pool of persons with a history of foot disease in the period was about 312,000.

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[2]The rate per year is over .323 percent because we did not have complete data for 1988.

This claims-based estimate may substantially underestimate the proportion of diabetic beneficiaries at risk for foot disease because it excludes diabetic beneficiaries who have not been hospitalized within the period. It may also be the case that California, Florida, and New York are not representative of the entire United States. If we assume that the number of diabetic Medicare beneficiaries over 65 years old with hospital stays for foot problems in any 1 year is one-fourth of all diabetic Medicare beneficiaries at risk for severe foot disease, then there may be up to 415,000 diabetic Medicare beneficiaries nationwide who meet the legislated clinical criteria for participation in the demonstration. This is nearly five times larger than the estimate based on the ADA rate, but 88 percent of the estimate based on the Palumbo and Melton rate.

Thus, somewhere between 415,000 and 472,000 persons appear to be clinically and programatically eligible for the demonstration benefit nationwide. Application of these nationwide estimates to the three demonstration States, California, New York, and Florida, yields estimates of between 96,000 and 110,000 beneficiaries eligible to enroll in the demonstration, which should provide a large enough pool to meet the sample size requirements of the evaluation.

2. Prevalence of Lower Extremity Amputations

Estimates of the annual number of foot amputations among diabetic Medicare beneficiaries range from the ADA's estimate of 12;400 in 1984 to the National Center for Health Statistic's (NCHS'S) estimate of 29,530 in 1985.

The ADA's estimate of 12,400 amputations and related procedures is based on 1984 Medicare claims data for two DRGs.[3] The ADA has not been able to provide further details on the development of this estimate or its reliability.

The NCHS estimates that there were 29,530 diabetes-related amputations for persons over age 65 in 1985.[4] This estimate is based on unpublished data for over 500 hospitals included in the 1985 National Hospital Discharge Survey.

A 1983 study by Most and Sinnock established an approximate 1 percent rate of amputation annually among diabetic patients over age 65 in six States between 1976 to 1978.[5] Assuming that this rate has remained unchanged over the past few years, and applying it to the estimate of 2.9 million Medicare beneficiaries with diagnosed diabetes in the United States in 1988, approximately 29,000 amputations would be estimated for 1988.

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[3]DRG's 285 and 287 were used by the ADA to screen Medicare claims.

[4]Linda Geiss, 8/24/88 telephone conversation.

[5]The Most and Sinnock study is based on hospital abstracts from Illinois, Maine, Minnesota, Ohio, Rhode Island, and South Carolina. The age-specific rate of lower extremity amputations per discharge from the study was multiplied by national estimates from the Health Interview Survey of age-specific discharge rates and divided by age-specific prevalence estimates for diabetes.

Most and Sinnock suggest that their estimate is conservative since diabetic conditions were thought to be under-reported on hospital discharge abstracts before prospective payment was introduced and because lower extremity amputation rates are higher among Blacks, who are under-represented in the study.

Using Medicare claims data for 1985, 1986, and 1987 for California, New York, and North Carolina, we found decreasing rates of diabetic foot amputations. The amputation rates for all Medicare enrollees in these States were .054 percent in 1985, .042 percent in 1986, and .030 percent in 1987.[6] The 1987 amputation rate applied to the United States as a whole in 1988 would yield 9,637 amputations among Medicare enrollees.

The Medicare claims based estimate for 1988 is considerably lower than either the ADA estimate of 12,400 or the estimate of 29,000 amputations from Most and Sinnock and NCHS. The lower rate results in large part from the reduced amputation rate in 1987 relative to earlier periods. The implication of the reduced rate (assuming that this is not an artifact of coding practices) is that therapeutic shoes will avert far fewer amputations than was previously estimated. Unless the cost of the alternative

[6]We do not know whether the decline in the rate of diabetic foot amputations over time reflects coding practice or clinical practice. Clinical reports suggest that amputations are now more aggressively averted than in the past.

medical therapy provided to avoid amputation is as great as the cost of amputation and rehabilitation, the therapeutic shoe benefit has a lower probability of resulting in cost savings than it had when amputation rates were higher.

3. Mortality

Palumbo and Melton (1985) report a 50 percent survival rate for 3 years after amputation and a 40 percent survival rate during the 5 years following amputation. Other authors concur that the mortality rate for diabetics who undergo extensive amputation is between 41 and 70 percent during the 5 years following surgery (Most and Sinnock, 1983). The probability of a patient with diabetes dying within 2 years after an extensive amputation is 72 percent, compared to 43 percent for diabetic patients with less extensive amputation (Steer et al., 1983).

Minnesota residents with diabetes who developed gangrene experienced only a 39 percent survival rate after 2 years. This figure is less than half of the expected survival rate for people of the same age and sex (Palumbo and Melton, 1985).

The implications of these very high mortality rates for a study of cost-effectiveness are two-fold.[7] If the demonstration targets the beneficiaries with the most severe foot disease, the patients may have very short life-expectancies. Under this condition, the opportunities for therapeutic shoes to reduce use of other services would be small, and the benefit would have a

[7]Although the effect of the benefit on mortality rates will be measured, no value will be placed on reduced mortality.

lower probability of showing cost-effectiveness during the beneficiaries' lifetimes. If the demonstration succeeds in targeting a group with less severe foot problems, on average, and if the therapeutic shoe benefit is clinically effective, mortality rates may be reduced by the benefit. This evaluation will not assess the long-term impacts of the therapeutic shoe benefit nor the long-term costs to Medicare. The evaluation will only measure the short-term cost effects.

B. CHARACTERISTICS OF MEDICARE BENEFICIARIES NOTIFIED

During the planning of the demonstration, we reviewed MADRS claims records for 1986, 1987, and part of 1988 for the three demonstration States to identify persons who met certain clinical criteria and should be notified about the demonstration. Among the persons who had one or more inpatient hospital stays during the period, we identified 416,156 who had a diabetic diagnosis, of whom 70,542 had a diagnosis consistent with severe foot disease. Table III.2 shows the diagnostic codes for the 70,542 beneficiaries. More than one-third (greater than 36 percent) had peripheral neuropathy, more than 30 percent had indications of gangrene, more than one-third had indications of a skin ulcer, over 11 percent had cellulitis, and just over 1 percent had skin infections in unspecified sites. All of these persons appeared to be candidates to meet the demonstration's clinical criteria for therapeutic shoe eligibility.

TABLE III.2

DIAGNOSTIC CODES AND DIAGNOSIS RELATED GROUPINGS OF
MEDICARE BENEFICIARIES IN THE DEMONSTRATION STATES
WHO WERE TARGETED TO BE NOTIFIED

Code Type	Code	Percent with this Code	Description of Code
DRG	285	3.6%	Amputation of Lower Limb, Diabetic
DRG	287	3.6%	Skin graft and Wound Debridement, Diabetic
ICD-9	250.6	35.9%	
ICD-9	337.1 + 250.X[a]	6.2%	
ICD-9	357.2	16.1%	Codes Indicating Diabetic Neuropathy with
ICD-9	713.5 + 250.X[a]	0.3%	Diabetes
ICD-9	358.1 + 250.X[a]	3.9%	
ICD-9	250.7	29.7%	
ICD-9	785.4 + 250.X[a]	26.4%	Codes Indicating Gangrene, with Diabetes
ICD-9	443.81 + 250.X[a]	6.5%	
ICD-9	250.8	33.9%	
ICD-9	707.1 + 250.X[a]	22.8%	Codes Indicating Skin Ulcer, with Diabetes
ICD-9	707.9 + 250.X[a]	0.4%	
ICD-9	681.1 + 250.Xa	0.0%	
ICD-9	682.7 + 250.X[a]	11.6%	Codes Indicating Cellulitis, with Diabetes
ICD-9	681.9 + 250.X[a]	<0.1%	
ICD-9	682.9 + 250.X[a]	0.4%	
ICD-9	686.9 + 250.X[a]	1.5%	Unspecified Local Infection of Skin
Total Number of Persons		70,542	

[a]250.X indicates any digit 0 through 9. These are codes for diabetes.

NOTE: Percentages add to more than 100 because beneficiaries could have multiple codes.

Since these patients had a hospital stay, they should probably be considered as having severe foot disease, rather than being at risk of it. Thus these data provide some expectations for the distribution of risk factors in the most severely affected part of the target group.

We wished to notify all of the targeted group of beneficiaries about the demonstration, except those who were deceased or ineligible because of current Medicare HMO coverage. After removal of 2,929 ineligible beneficiaries and selection of those who were alive at the time the notification was to be implemented, we found only 43,064 beneficiaries. Thus, 36 percent of the eligible group had died within 1 to 3 years of their hospital stay, consistent with the high mortality rates found in the literature. These data suggest that many of the demonstration's participants will die during the followup period.

C. BENEFICIARY CHARACTERISTICS AT ENROLLMENT

This section reviews the characteristics of the Medicare beneficiaries enrolled in the demonstration during the first 4 months of operations. A review of these characteristics may indicate whether the demonstration is enrolling the group that it was intended to target, and whether those enrolled are those for whom cost-savings can be generated as a result of wearing therapeutic shoes.

Upon enrollment in the demonstration, each beneficiary submits a prescription form that contains information on his or her duration of diabetes, presence of various foot conditions, history of therapeutic shoe use, and type of shoe prescribed. These data are summarized in Table III.3 for the 831 Medicare beneficiaries who were enrolled (415 in the control group and 416 in the treatment group). The statistics for these participants provide very preliminary estimates of the prevalence of different foot problems and the history of therapeutic shoe use for diabetic Medicare beneficiaries with severe foot disease. Over 40 percent of the participating beneficiaries have had diabetes for at least 15 years, while only 9 percent have had diabetes for 5 years or less. This is consistent with expectations, since foot problems tend to increase the longer diabetes has been present. Over one-fourth (28 percent) of the treatment and control group members had a previous amputation on one or both of their feet. This is the most serious of the risk factors for future amputation, showing that initial enrollees have a high rate of very serious foot problems. Each of the other four foot conditions (callus formation or history of callus formation with peripheral neuropathy, history of previous foot ulceration, poor circulation, and foot deformity with potential for ulceration) was present in 64 percent or more of the beneficiaries. That is

TABLE III.3

ELIGIBILITY CONDITIONS, ALL APPLICANTS

Eligibility Condition	Number	Percent
ESTIMATED DURATION OF DIABETES		
When diabetes was first recognized		
Less than five years ago	74	9%
5 to 10 years ago	201	24%
11 to 15 years ago	147	18%
More than 15 years ago	369	44%
Missing	40	5%
Total	831	100%
FOOT CONDITIONS		
Previous amputation of foot or part of foot		
One foot	175	21%
Both feet	61	7%
Either one or both feet	236	28%
Callus Formation or history of callus formation with peripheral neuropathy		
One foot	139	17%
Both feet	475	57%
Either one or both feet	614	74%
History of previous foot ulceration		
One foot	264	32%
Both feet	264	32%
Either one or both feet	528	64%
Poor Circulation		
One foot	99	12%
Both feet	509	61%
Either one or both feet	608	73%
Foot deformity with potential for ulceration		
One foot	138	17%
Both feet	454	55%
Either one or both feet	592	72%
HISTORY OF THERAPEUTIC SHOE USE		
Receiving physician prescription or recommendation for therapeutic shoes in the past 12 months	239	29%
Patients who currently have therapeutic shoes		
Depth-inlay shoes	130	16%
Custom-molded shoes	117	14%
Other	60	7%
Total	307	37%

TABLE III.3 (continued)

Eligibility Condition	Number	Percent
THERAPEUTIC SHOE PRESCRIPTION		
Type of shoe prescribed		
Depth-In Inlay shoe with insert	353	42%
Custom-molded shoe[a]	488	59%
Number	813	100%

SOURCE: Responses from completed Prescription Forms, August 1, 1989 through November 25, 1989.

[a] Ten participants were prescribed both types of shoes; hence the total number of depth-inlay and custom-molded shoes prescribed is ten greater than the number of eligible applicants.

to say, participants had an average of three foot conditions, any one of which would have made them eligible, indicating that, consistent with the group that was notified about the demonstration, a very high risk group was enrolled in the first 4 months, many of whom already have frank foot disease.

Perhaps consistent with the high rate of serious foot disease, at enrollment, 37 percent of the beneficiaries already had therapeutic shoes and 29 percent had received a physician prescription or recommendation for therapeutic shoes in the previous 12 months. These are relatively high rates, which, if maintained or exceeded in the noncovered (control) group during the demonstration period, would diminish the probability of the demonstration benefit being cost-effective.

At the time when the prescription forms were completed, more beneficiaries in the demonstration already had depth-inlay shoes than custom-molded shoes. Nevertheless, the physicians prescribed more custom-molded shoes for the participating beneficiaries (59 percent of the prescriptions) than depth-inlay shoes (42 percent of the prescriptions).[8] These relative rates of prescribing are somewhat different than anticipated. Based on clinical opinion, expected relative rates of prescriptions were about 70 percent depth-inlay and 30 percent custom-molded.

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[8]A few patients had prescriptions for both types of shoes, only one of which would actually be paid for by the demonstration.

Because the cost of custom-molded shoes is twice the cost of depth-inlay shoes, the likelihood of the benefit being cost-effective is lower when custom-molded shoes are prescribed at a higher rate than depth-inlay shoes.

D. CHARACTERISTICS OF PHYSICIANS PRESCRIBING SHOES

Approximately 75 percent of the physicians who treat diabetic patients are primary care physicians, many of whom are general and family practitioners.[9] Nevertheless, diabetic beneficiaries with foot disease are frequently treated by podiatrists and other specialists such as vascular surgeons, orthopedists, and endocrinologists as part of a comprehensive care plan. The specialists are more likely to be aware of the role of therapeutic shoes in diabetic foot care management.

The completed demonstration prescription forms include data identifying the specialties of the physicians who certify patient eligibility and prescribe the shoes. Tables III.4 and III.5 show that the distribution by specialty of the certifying and prescribing physicians is very similar. Over three-quarters of the forms have been completed by podiatrists. Orthopedic surgeons have completed between 7 and 8 percent of the forms, and doctors of internal medicine (including endocrinologists)

[9]This estimate is based on conversations with a panel of expert consultants.

TABLE III.4

SPECIALTIES OF CERTIFYING PHYSICIANS

Specialty	California	Florida	New York	Total
General or Family Practitioners	6%	3%	1%	3%
Internal Medicine, Nephrologist, Endocrinologist/Diabetologist	10%	11%	8%	10%
Orthopedic Surgeon	9%	7%	8%	8%
General or Vascular Surgeon	1%	3%	2%	2%
Podiatrist	74%	76%	80%	77%
Other Medical	<1%	<1%	2%	1%
Total	100%	100%	100%	100%
Total number with known specialty	163	184	200	547
Number unspecified or missing	65	98	107	270
Number of group practices	9	2	3	14
TOTAL NUMBER	237	284	310	831

SOURCE: Prescription Forms, August 1, 1989 through November 25, 1989.

NOTE: Percentages are for known specialties. Percentages may not add to 100 because of rounding.

TABLE III.5

SPECIALTIES OF PRESCRIBING PHYSICIANS

Specialty	California	Florida	New York	Total
General or Family Practitioners	5%	1%	<1%	2%
Internal Medicine, including Endocrinologists	8%	8%	6%	7%
Orthopedic Surgeons	8%	7%	8%	7%
General & Vascular Surgeons	1%	3%	1%	2%
Podiatrist	77%	82%	85%	81%
Other Medical	<1%	<1%	1%	1%
Total	100%	100%	100%	100%
Total number with known specialty	176	198	214	590
Number with Unspecified or Missing Specialty	52	82	93	227
Number of Group Practices	9	2	3	14
Total Number	237	284	310	831

SOURCE: Prescription Forms, August 1, 1989 through November 25, 1989.

NOTE: Percentages are for known specialties. Percentages may not add to 100 because of rounding.

certified 10 percent of diabetic patients.[10] General and family practitioners, who are believed to see the majority of patients, completed only 3 percent of the forms.

These physician characteristics are consistent with the severity of foot disease found among the early enrollees. Patients who have not developed ulcerations but who are at risk of severe foot disease are most likely to be seen by their primary care physicians only. In the longer run, meeting the demonstration's sample size targets will require enrolling patients other than those at the very highest risk, requiring more participation by primary care physicians.

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[10]These percentages exclude observations from the prescription forms which were missing information on the physician specialty.

IV. CONCLUSIONS

As was indicated at the start of the report, it is too early to present followup data on costs and cost-effectiveness of the therapeutic shoe benefit at the present. Chapter III summarized what is known about the prevalence of severe diabetic foot disease and the characteristics of the participating beneficiaries and physicians. Chapter II showed the participation rates of physicians and shoe suppliers. These findings and their implications for cost-effectiveness are summarized here.

The principal facts that are known at present are as follows:

- There are probably between 96,000 and 110,000 Medicare beneficiaries in the three demonstration States who are eligible for the demonstration benefit. This should be an adequate pool from which to enroll a sample of 27,400, the number required to be able to draw firm conclusions about the cost-effectiveness of the therapeutic shoe benefit.

- After 4 months of demonstration operations, 831 Medicare beneficiaries were enrolled. This is a lower enrollment rate than expected. If the enrollment rate does not increase, the sample size targets will not be met, which may affect the likelihood that cost impacts of the demonstration will be found if they exist. Given the way the OBRA 1987 enabling legislation was written, inconclusive findings would result in therapeutic shoes becoming a covered service under Medicare Part B in April 1993.

- The enrollees during the first 4 months have very severe foot disease. If beneficiaries with these characteristics are the only ones to enroll, the sample size may not be reached.

- Very few primary care practitioners are certifying patient eligibility and prescribing therapeutic shoes. More of these physicians must participate if the less

severely affected clinically eligible beneficiaries are to be enrolled, and if sample size targets are to be reached.

- A high rate of custom-molded shoes have been prescribed in the first 4 months. This is consistent with the very severe foot disease exhibited by the enrollees to date.

- About 20 percent of the podiatrists in the demonstration States requested information about the demonstration in order to prescribe for beneficiaries.

- One-fourth of the certified pedorthists in the demonstration States, the group that fits most depth-inlay shoes, have enrolled in the demonstration as shoe suppliers.

These findings indicate that the mandated demonstration has been implemented with the participation of physicians, shoe suppliers and beneficiaries, and with the support of the clinical community. Nevertheless, the relatively slow enrollment rate suggests the need for renewed and continuing publicity to physicians, to encourage them to enroll more of their patients, to beneficiaries to alert them to their eligibility, and to shoe suppliers to increase the access to shoe fitters. A vigorous new publicity campaign targeted at all three groups is currently underway.

More widespread participation among primary care and other physicians should yield a larger and more varied group of participating beneficiaries. It would also be helpful if more certified pedorthists enrolled as authorized shoe suppliers, since these professionals stock and supply depth-inlay shoes. One reason that has been given for nonparticipation by this group

is that the maximum allowed payment does not provide any profit margin, and that the shoes are supplied at cost. With the expansion of the demonstration benefit to include replacement inserts or modifications, shoe suppliers may have more leeway to make a profit, which may increase participation.

We conclude that there are not sufficient data to evaluate the cost-effectiveness of the therapeutic shoe benefit and the demonstration will need to be continued for 2 more years.

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APPENDIX A

DEMONSTRATION PRESCRIPTION FORM

MEDICARE THERAPEUTIC SHOE DEMONSTRATION PROGRAM

Certification and Prescription Form

[illegible]

A. PATIENT IDENTIFYING INFORMATION (PLEASE PRINT)

[illegible]

B. PHYSICIAN CERTIFICATION OF ELIGIBILITY FOR THERAPEUTIC SHOE DEMONSTRATION BENEFIT

[illegible]

C. HISTORY OF THERAPEUTIC SHOE USE (CIRCLE THREE THAT APPLY)

[illegible]

D. THERAPEUTIC SHOE PRESCRIPTION

RX: [illegible]

E. PRESCRIBER INFORMATION (PLEASE PRINT)

[illegible]

F. PATIENT CONSENT AGREEMENT (LARGE TYPE AND SPACING CONSULTATION APPLIES ON BACK OF FORM)

[illegible]

Patient Signature

PLEASE MAIL TOP TWO COPIES OF FORM TO:

MEDICARE THERAPEUTIC SHOE DEMONSTRATION
MATHEMATICA POLICY RESEARCH, INC.
P.O. BOX 2393
PRINCETON, NJ 08543-2393

APPENDIX B

ADVISORY PANEL MEMBERS

MPR has entered into consultant agreements with four experts on the diabetic foot, its care, and therapeutic shoes. They have provided advice on designing the prescription form, simplifying procedures for physicians to enroll their patients in the demonstration, and will review the reports on the demonstration.

Our medical consultants are:

William C. Coleman, D.P.M.
Chief, Podiatry Department
Department of Health and Human Services
Gillis W. Long Hansen's Disease Center
Carville, LA 70721
(504) 642-4710

Dr. Coleman has faculty appointments at the Prosthetic-Orthotic Center at Northwestern University Medical School, the William School College of Podiatric Medicine, The Ohio College of Podiatric Medicine, the California College of Podiatric Medicine and the New York College of Podiatric Medicine.

Marvin E. Levin, M.D.
732 Fairfield Lake Dr.
Chesterfield, MO 63017

Dr. Levin is an endocrinologist who holds an appointment as professor of clinical medicine at the Washington University School of Medicine, St. Louis, Missouri. Dr. Levin is also an associate director of the Metabolism/Diabetes Clinic at Washington University and holds appointments at several hospitals in St. Louis, including Barnes Hospital, The Jewish Hospital of St. Louis, and

St. Louis Children's Hospital. He is the editor of a major text on the problem The Diabetic Foot.

Anthony L. McCall, M.D., Ph.D.
Director, Diabetes Program
Portland VA Medical Center
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P.O. Box 1034
Portland, OR 97207
(503) 273-5015

In addition to directing the Diabetes Program at the Portland VA Medical Center, Dr. McCall is an Associate Professor of Medicine, Neurology, and Cell Biology/Anatomy at the Oregon Health Sciences University.

Herb S. Steb, C. Ped.
President, Walk-Well Professional Shoe Fitters
20 Mine Brook Road
Bernardsville, NJ 07924
(201) 766-9766

Mr. Steb is a past president of the Prescription Footwear Association and president-elect of the Board for Certification in Pedorthics. Mr. Steb holds appointments as consultant and faculty member at New York University Post Graduate School of Medicine, Prosthetic-Orthotic Department and at Northwestern University Medical School Prosthetic-Orthotic Center. He is a practicing pedorthist.

The Center for Disease Control, Diabetes Control Unit has also provided epidemiological and diabetes advice about diabetes treatment programs.

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